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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,521	03/06/2001	Martin A. Lee	1498-121	1411

7590

09/27/2002

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EXAMINER

WHISENANT, ETHAN C

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,521	LEE ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 12-16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIM OBJECTIONS

1. **Claim(s) 2 and 9** is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

2. **Claim(s) 12-16** is/are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on a multiple dependent claim. See MPEP § 608.01(n). Accordingly, these claim(s) have not been further treated on the merits.

35 USC § 112- 2ND PARAGRAPH

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

4. **Claim(s) 1-11** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the phrase "said reaction mixture" on line 9 lacks proper antecedent basis.

Claim 9 is confusing because it is dependent on Claim 8 and it is unclear to the examiner how in claim 9 further limits the claim 8. Note that in Claim 8 the temperature probe is a single stranded sequence which forms a loop while claim 9 requires that the reporter and quencher be on different strands of a dsDNA molecule. Please clarify. Please note that in the prior art rejections below Claim 9 has been interpreted as if it were dependent on Claim 7 instead of Claim 8.

35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

7. **Claim(s) 1-2, 6-7 and 9 is/are** rejected under 35 U.S.C. 103(a) as being unpatentable over Hiyoshi et al. (1994) in view of Livak [US 5,736,333 (1998)].

Claim 1 is drawn to a method of monitoring the temperature of a biochemical reaction wherein said method comprises two steps: to begin a biochemical reaction is performed in the presence of fluorescently labeled temperature probe DNA which probe comprises a double stranded region which denatures at a predetermined temperature and wherein the fluorescent label of said temperature probe sequence being arranged so that a detectable signal occurs at the point at which denaturation of the double stranded region occurs. Finally, in step two the fluorescence of the reaction mixture is monitored in order to determine when said predetermined temperature has been reached.

Hiyoshi et al. teaches a method comprising all of the limitations of Claims 1-2, 6-7 and 9 except these authors do not explicitly teach monitoring the temperature of a biochemical reaction, rather Hiyoshi et al. teach a method for monitoring DNA denaturation. However, as evidenced by Livak et al. it was well known in the art to monitor the temperature of a biochemical reaction (i.e. PCR). See at least, for example, Column 1, beginning at line 33- Column 2, line 3. Therefore, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Hiyoshi et al. wherein their system is used to monitor the temperature of a

biochemical reaction. The ordinary artisan would have been motivated to modify Hiyoshi et al. with Livak et al. to arrive at the claimed invention in view of Figure 5 of Hiyoshi wherein it is readily apparent that temperature can be monitored as a function of increasing/decreasing fluorescence of the PCR product.

8. Claim(s) 1-2 and 4-6 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ririe et al. (FEB 1997) in view of Livak et al. [US 5,736,333 (1998)].

Ririe et al. teach a method comprising all of the limitations of Claim 1-2 and 4-6 except these authors do not explicitly teach monitoring the temperature of a biochemical reaction, rather Ririe et al. teach monitoring DNA melting curves (i.e. denaturation) using the intercalating fluorescent dye, SYBR Green I. However, as evidenced by Livak et al. it was well known in the art to monitor the temperature of a biochemical reaction (i.e. PCR). See at least, for example, Column 1, beginning at line 33- Column 2, line 3. Therefore, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Ririe et al. wherein their system is used to monitor the temperature of a biochemical reaction. The ordinary artisan would have been motivated to modify Ririe et al. with Livak et al. to arrive at the claimed invention in view of Figures 1-5 of Ririe et al. wherein it is readily apparent that temperature can be monitored as a function of increasing/decreasing fluorescence of the PCR product.

9. Claim(s) 1-3 and 6-8 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over by Tyagi et al [US 5,925,517(1999)] in view of Livak et al. [US 5,736,333 (1998)].

Tyagi et al teach a method comprising all of the limitations of Claim 1-3 and 6-8 except these authors do not explicitly teach monitoring the temperature of a biochemical reaction, rather Tyagi et al teach monitoring the amount of PCR product produced using a molecular beacon probe. However, as evidenced by Livak et al. it was well known in the art to monitor the temperature of a biochemical reaction (i.e. PCR). See at least, for example, Column 1, beginning at line 33- Column 2, line 3. Therefore, absent an unexpected result, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Tyagi et al. wherein their system is used to monitor the temperature of a biochemical reaction. The ordinary artisan would have been motivated to modify Tyagi et al. with Livak et al. to arrive at the claimed invention in view of Figures 3-8 of Tyagi et al. wherein it is readily apparent that temperature can be monitored as a function of increasing/decreasing fluorescence of the biochemical reaction.

CONCLUSION

10. Claim(s) 1-16 is/are rejected and/or objected to for the reason(s) set forth above.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.


ETHAN C. WHISENANT
PRIMARY EXAMINER

SEARCH NOTES

20 SEP 02

09/786,521

Databases searched: USPATFULL via EAST, Caplus, Medline, Biosis

Application(s) Reviewed: Parental Application(s) shown on BIBDATSHEET

Search terms:

Inventor(s) : e.g. Lee M?/au

Monitor\$ near temperature and (PCR or reaction)

Fluorescent\$

Haipin probe? and/or stem adj loop near probe?

FRET

Double stranded DNA or dsDNA or Double stranded nucleic

Intercalat\$